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IN THE UNITED STATES DISTRICT COURT

THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

ELIZABETH A. HOLMES and
RAMESH "SUNNY" BALWANI,

Defendants.

Case No. cr-18-00258-EJD

MR. BALWANI'S REPLY IN SUPPORT OF DEFENDANTS' MOTION TO COMPEL DISCOVERY AND BRADY MATERIALS

Date: June 28, 2019
Time: 10 a.m.
CTRM: 4

Hon. Edward J. Davila

I. INTRODUCTION

Mr. Balwani files this reply specifically to address the government's suggestion that an Order granting this Motion is unnecessary, on the theory that the Court should rely on the FDA and CMS to make satisfactory document productions only in response to subpoenas Mr. Balwani served in the parallel SEC civil case. In fact, the agencies' responses to Mr. Balwani's civil subpoenas show that the requested Order is essential to ensure timely production and efficient progress in this criminal case.

Mr. Balwani has a unique perspective on this issue. Although Mr. Balwani served CMS and FDA with civil subpoenas in September 2018, neither agency has yet to begin meaningful compliance with the requests. Now, hoping to avoid a Court order directing the government to provide defendants with documents crucial for this case, particularly internal communications, the government submits letters from the agencies describing their intent to *begin* producing unspecified documents weeks from now—more than *nine months* after service of the subpoenas in the civil case. The agencies' letters should provide the Court with cold comfort. They promise only a process that would allow the agencies to choose or even cherry-pick what to collect and produce while continuing to object to civil discovery, laying the foundation for still more motion practice.

The Court should not rely on assurances that the agencies will now do what they should have done many months ago. Instead, the Court should issue an order in this case requiring the government to produce all material in the possession of CMS and FDA responsive to defendants' requests, including all internal correspondence from all custodians involved in the agencies' interactions with Theranos. An order from this Court pursuant to Rule 16 and *Brady* is required to honor Mr. Balwani's Constitutional rights to a fair trial and to present a complete defense in this criminal case where he faces serious charges with the full might and resources of the United States government arrayed against him. *Crane v. Kentucky*, 476 U.S. 683, 690 (1986). The internal communications within CMS and FDA about Theranos and its business and laboratory operations could not be more central to this case. Indeed, if the DOJ is actually trying to get the agencies to produce all of the required documents, it should welcome an order from this Court

requiring production. The agencies' foot-dragging over the last nine months, discussed below, demonstrate that only an Order from this Court in this case will lead to full production.

II. ARGUMENT

A. The Agencies Have Failed to Timely Comply with Mr. Balwani's Subpoenas.

On September 12, 2018, Mr. Balwani issued subpoenas in the SEC matter to the FDA and CMS. Since then, Mr. Balwani has made various accommodations to reduce the burden on the agencies and expedite production. In particular, Mr. Balwani (1) initially offered to narrow the CMS subpoena to the period 2013 to 2016, *see* Cazares Decl. Ex. A at 2-3; (2) tried to identify relevant custodians, even with limited information, to focus searches for internal communications, *id*. at 3; (3) negotiated a protective order to cover the agencies' future productions, SEC Dkt. 83; and (4) obtained a waiver from the Theranos assignee as to production of documents containing trade secrets and confidential commercial information, Opp'n Ex. F.

Despite these accommodations, the FDA and CMS have produced a mere 161 documents in response to Mr. Balwani's subpoenas—a sparse production, given their years of regulatory interaction with Theranos, that did not include internal communications. Cazares Decl. ¶ 3. Both agencies have put forward a plethora of objections to avoid producing all of their internal communications relating to Theranos. Claims from the agencies that they produced other documents that the prosecution wanted are obviously insufficient.

After thus being rebuffed for over seven months, Mr. Balwani, on April 2, 2019, served counsel for the FDA and CMS with draft letter motions to compel production of documents pursuant to the subpoenas. Cazares Decl. Ex. B at 3. The prospect of motions briefly brought the agencies to the table. On April 17, 2019, the agencies' counsel agreed to a further meet and confer with Mr. Balwani regarding the proposed motions to compel. Cazares Decl. Ex. B at 1. Two days later, however, the government filed its motion to stay discovery in the SEC case. SEC Dkt. No. 67. Although the Court clearly stated at the April 22, 2019, status conference that

SEC discovery would continue pending disposition of the stay motion, counsel for the agencies rebuffed efforts to discuss the subpoenas until the Court decided the motion. *Id*. Ex. C.[1]

Promptly after the Court denied the Motion to Stay the SEC case, Mr. Balwani again requested a meet and confer. *Id*. Ex. D. On June 21, 2019, new counsel for the FDA and CMS responded with an email that, among other things, reported that "CMS and FDA currently anticipate that they will *begin* additional productions . . . in *approximately* a month." *Id*. Ex. E at 1 (emphasis added). But the email called that "estimate" a mere "goal," suggesting the agencies might not even start producing documents in July if they have "technical or other difficulties" or if "necessary resources" are not "available." *Id*. Moreover, the California Department of Public Health ("CDPH") announced with the filing of the government's opposition brief that they lost crucial documents from their December 2013 inspection of Theranos's clinical laboratory, *see* Opp'n Ex. E, an inspection carried out by CDPH as the agent of CMS. *See* 45 C.F.R. § 2.2. The lost documents are officially federal records, *see* Cazares Decl. ¶ 11, showing that CMS even failed to properly honor the litigation hold that DOJ directed them to put in place.[2]

Thus, over nine months after serving subpoenas for documents vital to his defense, Mr. Balwani has neither the documents nor a firm commitment for their production—and finds that some agency documents have even been lost.

[1] Even with the Motion to Stay pending, Mr. Balwani obtained the agencies' agreement to a Supplemental Protective Order for FDA and CMS Information, SEC Dkt. 83, and secured the Theranos assignee's waiver of trade secrets and other protections, which the FDA and CMS demanded, Opp'n Ex. F.

[2] Under federal law, employees of state regulatory agencies engaged in "performing survey, certification, or enforcement functions" are deemed "employees" of HHS, just like CMS employees. 45 C.F.R. § 2.2. Now, faced with this motion, CMS represents that documents related to the 2013 CLIA survey by CDPH "are no longer available," even though the government issued a litigation hold to the HHS Office of General Counsel regarding *all* communications by CMS employees, Mot. Ex. 8, which includes the CDPH surveyor who performed the 2013 Theranos CLIA survey. Thus, materials relevant to this action now appear to be "unavailable" due to CMS inaction and its failure to previously secure CMS records of surveys conducted on its behalf.

B. The Agencies' Letters Do Not Provide Sufficient Assurances to Avoid an Order.

The agencies' failure to comply in any meaningful way with the September 2018 subpoenas in the SEC case provides the lens through which the Court should view the government's argument that the Court should now trust the FDA and CMS to produce documents they should have produced months ago. *See* Opp'n 5-6. The FDA and CMS letters filed with the Court (Opp'n Exs. C, D) amount to nothing more than pledges to review documents, reassert objections, and use discretion in deciding what to produce. They thus promise nothing more than a continuation of the same conduct.

FDA. The FDA's letter of June 7, 2019 (Opp'n Ex. C) commits to nothing. It amounts to a list of excuses to avoid production, and promises only continued disputes.

The FDA begins with the erroneous assertion that most of the requested materials are irrelevant to this case. Opp'n Ex. C at 2. It then argues "burden," saying that it identified 62,000 documents based on key word searches of forty-five custodians' files, which now must be subjected to a laborious "line-by-line" review for "privilege and other protections." *Id*. The FDA says it intends to use this process to redact: (1) trade secret information; (2) confidential commercial information; (3) attorney-client communications; (4) attorney work product; (5) personal privacy information; (6) privileged investigatory files; and (7) deliberative process and/or other protected information. *Id*. at 3.

The FDA's invocation of the deliberative process privilege reneges on its prior agreement, in the discussions with Mr. Balwani regarding the subpoena in the SEC case, to waive deliberative process privilege claims and produce internal FDA communications. Cazares Decl. Ex. F at 3. Indeed, the FDA produced several internal communications during the government investigations, *id.* ¶ 10, but now states for the first time, in its June 7, 2019 letter, that it will withhold materials under a claim of deliberative process privilege. Opp'n Ex. C.

Further, the FDA says it must take the time to manually de-duplicate previously produced documents (Opp'n Ex. C at 2), an unnecessary process that appears calculated to further delay production. The FDA concedes the Theranos assignee's waiver of trade secret and commercial information protections eliminates its obligation to redact some material, but asserts it will not

re-produce responsive materials that it previously produced with heavy redactions in response to FOIA requests. *Id*. at 3. In short, the FDA's letter gives the Court no assurance as to how much (*if any*) substantive information the FDA will produce, and when the production will occur.

The requested Order would overcome most of the hurdles the FDA has erected to delay production. As the FDA admits, the "need to redact privileged and otherwise confidential information from the newly-collected documents" vanishes with entry of an appropriate Order. *Id*. at 3 (FDA "cannot lawfully produce any responsive documents that would reveal such information *absent a court order*") (emphasis added); *see United States v. W.R. Grace*, 455 F. Supp. 2d 1140, 1148 (D. Mont. 2006) (granting discovery order and rejecting government trade secret, privacy, and deliberative process privileges claims for withholding agency documents); *Agility Pub. Warehousing Co. v. Dep't of Def.*, 110 F. Supp. 3d 215, 228-29 (D.D.C. 2015) (holding that order granting motion to compel subpoena compliance constitutes "other appropriate legal authorization" permitting disclosure of trade secrets under 18 U.S.C. § 1905).

Mr. Balwani asks the Court to enter an Order in this case to resolve the FDA's concerns and expedite production. Otherwise, the parties will be before the Court months from now to address the same issues that have impeded Mr. Balwani's efforts to obtain FDA records since September 2018 in the SEC case.

CMS. Like the FDA, CMS seeks to avoid an Order by suggesting it will do better than it has over the last nine months. Opp'n Ex. D. But the CMS letter likewise rings hollow.

CMS has produced a grand total of 43 documents in response to the September 2018 subpoena. Cazares Decl. ¶ 3. As noted above, claims from CMS that it produced other documents that DOJ or SEC wanted for their joint investigation are not sufficient. During the lengthy meet and confer process dating from the fall of 2018, CMS steadfastly refused to produce *any* internal communications relating to Theranos. Cazares Decl. Ex. G at 2. CMS now says it will produce internal communications relating to Theranos, but it is not clear whether CMS is now agreeing do more than search for communications for the few custodians it calls the "CLIA group." Opp'n Ex. D. CMS's past conduct, combined with its silence on which

document custodians it will search, indicates that it may be planning to unilaterally limit the search, cherry-pick custodians and their documents, and then claim full compliance.

Absent an order from this Court, CMS will likely revert to the same objections and delays that have stalled Mr. Balwani's efforts to obtain its records. The Court should enter an Order requiring CMS to produce without limitations.

III. CONCLUSION

For the foregoing reasons, the Court should reject the government's proposed alternatives to meet its discovery obligations in this criminal case and grant the requested order compelling disclosure by the government of the requested materials in this case.

DATED: June 24, 2019

Respectfully submitted,

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